UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,752	07/19/2004	Ratan K. Chaudhuri	Merck-2896	1050

23599 7590 10/03/2007

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

MAIL DATE	DELIVERY MODE
10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,752	CHAUDHURI ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/18/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on July 18, 2007.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-32 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "based on the weight of the extract" in Claim 1, line 2. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on July 18, 2007 now recite a "A standardized extract of Emblica officinalis consisting essentially of over 40% by weight based on the weight of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids based on the weight of the extract". However, the specification as originally filed provides only for compositions comprising a standardized extract of *Emblica officinalis* consisting

essentially of over 40% by weight Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concept for compositions comprising a standardized extract of *Emblica officinalis* consisting essentially a claim-designated percentage amount of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a claim-designated percentage amount of flavonoids, with regard to Claim 1. There is only one exemplified composition wherein the claimed composition is a standardized extract of *Emblica officinalis* consisting essentially of over 40% by weight based on the weight of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids (wherein the claim-designated percentage amounts of the claim-designated ingredients are based on the total weight of the composition) versus a composition of a standardized extract of *Emblica officinalis* consisting essentially of over 40% by weight of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids based on the weight of the extract. This is not sufficient support for the new aforementioned genera/genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1-32 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied rejections provided herein are necessitated by amendment. Applicants arguments have been thoroughly considered, however, the rejection stands for the reason set forth in the previous Office action and for the reason set forth herein.

Applicants argues that the percentage of the ingredients recited in each of Claims 1-3, 11 and 15-17 are clearly based on weight when reviewing the application as a whole. However, Applicant's arguments are not persuasive because the metes and bounds of the claim-designated ingredients are not set forth in terms of either "by weight" or "by volume" percentage amount of **the total weight or the total volume of the composition**. The Office maintains that amounts of ingredients in terms of mass or weight when not given in relation to the overall mass or weight of the composition do not provide any indication as to what percentage of the composition comprises the claimed

ingredients; and therefore, it is unclear as to what amounts of each ingredient Applicant is claiming in the invention. Thus, the metes and bounds of Claims 1–3, 11 and 15-17 are remain uncertain because the percentage amounts of the ingredients are not set forth in terms of either "by weight" or "by volume" percentage amount of the total weigh of the composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 1 are rendered vague and indefinite by the phrase "based on the weight of the extract of Emblicanin A" because it is unclear as to what constitutes an extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin". The lack of clarity renders the claim very confusing and ambiguous considering that the preamble recites a standardized extract of *Emblica officinalis*.

Claim 8 recites the limitation "the extract of flavonoids" in line 3. There is insufficient antecedent basis for this limitation in the claim because nowhere in Claim 1 from which Claim 8 indirectly depends is there a recitation of an "extract of flavonoids".

Claim 10 recites the limitation "said composition" in line 2. There is insufficient antecedent basis for this limitation in the claim because nowhere in Claim 1 from which Claim 10 directly depends is there a recitation of the limitation "composition".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 28, 2007

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on July 18, 2007.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-32 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "based on the weight of the extract" in Claim 1, line 2. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on July 18, 2007 now recite a "A standardized extract of Emblica officinalis consisting essentially of over 40% by weight based on the weight of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids based on the weight of the extract". However, the specification as originally filed provides only for compositions comprising a standardized extract of *Emblica officinalis* consisting

essentially of over 40% by weight Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concept for compositions comprising a standardized extract of *Emblica officinalis* consisting essentially a claim-designated percentage amount of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a claim-designated percentage amount of flavonoids, with regard to Claim 1. There is only one exemplified composition wherein the claimed composition is a standardized extract of *Emblica officinalis* consisting essentially of over 40% by weight based on the weight of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids (wherein the claim-designated percentage amounts of the claim-designated ingredients are based on the total weight of the composition) versus a composition of a standardized extract of *Emblica officinalis* consisting essentially of over 40% by weight of the extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin, and not more than about 1% by weight of flavonoids based on the weight of the extract. This is not sufficient support for the new aforementioned genera/genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1-32 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied rejections provided herein are necessitated by amendment. Applicants arguments have been thoroughly considered, however, the rejection stands for the reason set forth in the previous Office action and for the reason set forth herein.

Applicants argues that the percentage of the ingredients recited in each of Claims 1-3, 11 and 15-17 are clearly based on weight when reviewing the application as a whole. However, Applicant's arguments are not persuasive because the metes and bounds of the claim-designated ingredients are not set forth in terms of either "by weight" or "by volume" percentage amount of **the total weight or the total volume of the composition**. The Office maintains that amounts of ingredients in terms of mass or weight when not given in relation to the overall mass or weight of the composition do not provide any indication as to what percentage of the composition comprises the claimed

ingredients; and therefore, it is unclear as to what amounts of each ingredient Applicant is claiming in the invention. Thus, the metes and bounds of Claims 1–3, 11 and 15-17 are remain uncertain because the percentage amounts of the ingredients are not set forth in terms of either "by weight" or "by volume" percentage amount of the total weigh of the composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 1 are rendered vague and indefinite by the phrase "based on the weight of the extract of Emblicanin A" because it is unclear as to what constitutes an extract of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin". The lack of clarity renders the claim very confusing and ambiguous considering that the preamble recites a standardized extract of *Emblica officinalis*.

Claim 8 recites the limitation "the extract of flavonoids" in line 3. There is insufficient antecedent basis for this limitation in the claim because nowhere in Claim 1 from which Claim 8 indirectly depends is there a recitation of an "extract of flavonoids".

Claim 10 recites the limitation "said composition" in line 2. There is insufficient antecedent basis for this limitation in the claim because nowhere in Claim 1 from which Claim 10 directly depends is there a recitation of the limitation "composition".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele C. Flood.

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 28, 2007